UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

| AMERICAN | MEDICAL SYSTEMS, |) | | | | |
|----------|-------------------|-----|-------|--------|-----|--------------|
| INC. and | LASERSCOPE, INC., |) | | | | |
| | Plaintiffs |) | | | | |
| | |) | | | | |
| | v. |) (| CIVIL | ACTION | NO. | 08-30061-MAP |
| | |) | | | | |
| BIOLITEC | , INC., ET AL., |) | | | | |
| | Defendants |) | | | | |

MEMORANDUM AND ORDER RE: PLAINTIFFS' MOTION THAT THE
ASSERTED CLAIMS ARE NOT INVALID; PLAINTIFFS' MOTION FOR
SUMMARY JUDGMENT OF INFRINGEMENT; PLAINTIFFS' MOTION FOR
PARTIAL SUMMARY JUDGMENT OF FALSE ADVERTISING AND UNFAIR AND
DECEPTIVE TRADE PRACTICES; DEFENDANTS' MOTION FOR SUMMARY
JUDGMENT OF INVALIDITY, NONINFRINGEMENT, NONWILLFULINESS,
AND NO FALSE ADVERTISING OR UNFAIR TRADE PRACTICES;
DEFENDANTS' MOTION TO STRIKE; PLAINTIFFS' MOTION TO
PRECLUDE, AND DEFENDANTS' MOTION TO COMPEL
(Dkt. Nos. 166, 169, 174, 179, 184, 188, 218)

March 30, 2011

PONSOR, D.J.

I. INTRODUCTION

This intricate and lavishly briefed piece of patent litigation turns on the proper construction of a single two-letter word: "on." One may say that a dictionary rests "on" a table but, if an apple is then placed on the dictionary, is it, too, "on" the table? In one sense it is; in another, it is not. Here, the patented product claims, as an essential feature, a transmitting surface located "on" the tip of a waveguide. The accused device discloses a

transmitting surface located "on" a cap placed over the tip of the waveguide. For the reasons set forth below, this critical difference mandates a finding that, as a matter of law, Defendants' device does not infringe Plaintiffs' patent. The court will therefore allow Defendants' motion for summary judgment on most of Plaintiffs' complaint.

The background of this case may be briefly summarized. In 2008, Plaintiffs American Medical Systems, Inc. ("AMS") and Laserscope, Inc. filed a six-count complaint against Defendants Biolitec, Inc. ("Biolitec"), CeramOptec Industries, Inc., CeramOptec GmbH, AndaOptec, Ltd., and Biolitec SIA alleging: Count I, infringement of U.S. Patent No. 6,986,764 ("the '764 Patent") against all Defendants except Biolitec; Count II, infringement of U.S. Patent No. 5,428,699 ("the '699 Patent") against all Defendants; Count III, false advertising under the Lanham Act, 15 U.S.C. § 1125(a), against Biolitec; Count IV, unfair and deceptive trade practices in violation of Mass. Gen. Laws ch. 93A, §§ 2, 11, against Biolitec; Count V, untrue and misleading advertising in violation of Mass. Gen. Laws ch. 266, § 91, against Biolitec; and Count VI, unfair competition against Biolitec. (Dkt. No. 72, First Am. Compl.)

¹ Two additional defendants, Biolitec AG and ForTec Medical, Inc., were dismissed from the case in 2009. (Dkt. Nos. 94, 145.)

As of now, the litigation in this case has involved only Counts II through VI, namely the claims arising out of alleged infringement of Patent '699.² Plaintiffs seek a judgment that Defendants have infringed Patent '699, a permanent injunction prohibiting the infringement, treble damages arising out of the infringement, an injunction against promotion of the accused product, treble damages arising out of damages incurred due to past promotion and to the alleged spread of misinformation about Plaintiffs' product, and attorneys' fees.

On October 28, 2009, the court issued its Memorandum and Order Regarding Construction of Patent Claims pursuant to Markman v. Westview Instruments, Inc., 52 F.3d 967, 976 (Fed. Cir. 1995). Am. Med. Sys., Inc. and Laserscope, Inc. v. Bioletic, Inc., et al., 666 F. Supp. 2d 216 (D. Mass. 2009) (hereinafter "Markman Order"). The parties filed cross motions for summary judgment on Counts II-VI and

² Count I against all Defendants except Biolitec is the only claim in this case arising out of alleged infringement of the '764 Patent. In 2007, Plaintiffs filed suit against Biolitec alleging infringement of the '764 Patent, 07-cv-30109-MAP. Although the court allowed Biolitec's motion for summary judgment of non-infringement, the Federal Circuit reversed the decision. See Am. Med. Sys. Inc. and Laserscope v. Bioletic, Inc., 618 F.3d 1354 (Fed. Cir. 2010). The parties are currently engaged in discovery in that case with a hearing scheduled for dispositive motions set for November 29, 2011.

appeared for argument on those motions in September 2010.

Defendant Biolitec's motions for summary judgment were filed collectively (Dkt. No. 179). Plaintiffs' separate motions are: Motion for Summary Judgment of Validity (Dkt. No. 166); motion for Summary Judgment of Infringement of the '699

Patent (Dkt. No. 169); Motion for Partial Summary Judgment of False Advertising under the Lanham Act and Unfair and Deceptive Trade Practices (Dkt. No. 174).

For the reasons that follow, the court will allow Plaintiffs' Motion for Summary Judgment of Validity of the '699 Patent (Dkt. No. 166) but will deny the remainder of Plaintiffs' motions (Dkt Nos. 169 and 174). The court will deny Defendant Biolitec's motion as to invalidity but will allow the balance of the motion as to Counts II-VI (Dkt. No. 179).

II. BACKGROUND

On June 27, 1995, Plaintiff Laserscope, a wholly owned subsidiary of Plaintiff AMS, and inventor Russell Pon obtained a patent that described a side-firing laser probe that delivered laser energy to prostate tissue to vaporize or ablate it and to reduce the size of the organ. U.S. Pat. No. 5,428,699 (June 27, 1995). The patent was entitled "Probe Having Optical Fiber for Laterally Directing Laser Beam." (Dkt. No. 72, Ex. 3.) This laser procedure is used

to treat Benign Prostatic Hyperplasia ("BPH"), a condition in which an enlarged prostate compromises functioning of the bladder and urethra. Vaporization, or ablation, of some of the prostate tissue reduces the size of the prostate.

The side-firing laser system utilizes a laser probe that consists, principally, of a fiberoptic core surrounded by a cladding or sheath, which may or may not be surrounded by other layers of material. Laser light travels along the fiber core before reflecting off a surface at an angle such that ninety percent of the laser energy or more passes through a particular area on the transmitting surface and ultimately hits the prostate tissue. The cladding has a lower index of refraction than the fiber core to ensure that the laser light is internally reflected back into the fiber and does not "leak" before it is reflected onto the prostate tissue.

Plaintiff AMS has the exclusive right to make, use, sell, and offer to sell the '699 Patent. Plaintiff AMS manufactures products using the '699 Patent called the GreenLight PV Laser System and the GreenLight HPS Laser Platform ("GreenLight"), which it sells to urologists for the treatment of BPH. In 2004, Defendant Biolitec began to sell a product to treat BPH called the Evolve SLV SideFiber laser delivery probe ("Evolve"), which also employs a laser

to ablate enlarged prostate tissue. Plaintiffs allege that Defendant Biolitec's Evolve laser system infringes the '699 Patent. Plaintiffs further allege that Defendant Biolitec employed deceptive sales practices and false advertising. The facts pertaining to these allegations will be discussed below.

III. DISCUSSION

A. <u>Legal Standard</u>.

Summary judgment is appropriate when there is no genuine issue of material fact and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c). The court views the evidence in the light most favorable to the non-moving party and the moving party bears the burden of establishing the absence of a genuine issue of material fact. Celotex Corp. v. Catrett, 477 U.S. 317, 322-23 (1986). "This standard is not changed when the parties bring cross-motions for summary judgment, each nonmovant receiving the benefit of favorable inferences." Chevron U.S.A., Inc. v. Mobil Producing Tex. & N.M., 281 F.3d 1249, 1253 (Fed. Cir. 2002). The parties agree that no material facts are in dispute and that summary judgment at this stage of the proceedings is appropriate.

B. <u>Invalidity</u>.

The court will turn first to the issue of invalidity.

Defendants allege that the '699 Patent is invalid as anticipated, as obvious, and for failure to meet the written description. The burden on Defendants to demonstrate invalidity is heavy. As the Federal Circuit has stated, "an issued patent is entitled to a statutory presumption of validity. . . . [C]lear and convincing evidence [must] be shown to invalidate a patent." Datamize, LLC v. Plumtree
Software, Inc., 417 F.3d 1342, 1347-48 (Fed. Cir. 2005).

1. Anticipation.

Defendants allege that two patents, Japanese Patent No. 3-63377 (JP '377) and U.S. Patent No. 4,740,047 to Abe (Abe '047), and disclose every limitation of claims 1, 2, 4, 5, 25, 26, 30, and 33 of the '699 Patent.

The '699 Patent references the prior art in Abe '047

 $^{^3}$ One of the principal inventors of Abe `047 was also an inventor of JP `377, and the former incorporates into its disclosure all of the limitations of the latter. (Dkt. No. 171, Ex. 6, Griffin Rep. ¶ 30.)

⁴ Plaintiffs filed a complaint alleging infringement of the '699 Patent against a different defendant in the United States District Court of the District of Minnesota. Although the Minnesota court found that the '699 Patent was not anticipated by a number of patents raised by the alleged infringer in that case, the court held that genuine issues of material fact remained as to whether JP '377 anticipated the '699 Patent. Am. Med. Sys. v. Laser Peripherals, LLC, 712 F. Supp. 2d 885, 918 (D. Minn. 2010). With the benefit of additional filings by the United States Patent and Trademark Office, this court is now in a position to render summary judgment on this issue.

and explains that a flaw in the design of Abe '047 was that it could melt at high temperatures, causing burning of the probe and even of the patient. U.S. Pat. No. 5,428,699, column 1, lines 51-65. The '699 Patent sought to improve on Abe '047 by providing "an improved optical fiber tip for laterally directing a laser beam . . . compris[ing] a waveguide, such as an optical fiber, having a tip." Id. at column 2, lines 3-6. Plaintiffs assert that the following limitations are not present in Abe '047 or JP '377 but are disclosed by the '699 Patent in independent claims 1 and 25 and their dependent claims, which describe: (1) greater than ninety percent of radiation reflected being transmitted in the desired lateral direction; (2) a reflecting surface for internally reflecting electromagnetic radiation; (3) a transmitting surface on the tip of the waveguide; and (4) the cladding-to-core ratio required by claim 5 and its dependent claims. (Dkt. No. 167, Pls.' Mem. in Supp. of Mot. for Summ. J., at 11.)

a. Legal Standard for Anticipation.

Both parties have moved for summary judgment on the issue of anticipation under 35 U.S.C. § 102. "A determination that a patent is invalid as anticipated under 35 U.S.C. § 102 requires that a prior art reference disclose every limitation of the claimed invention, either explicitly

or inherently." Liebel-Flarsheim Co. v. Medrad, Inc., 481

F.3d 1371, 1381 (Fed. Cir. 2007). The "dispositive question regarding anticipation [is] whether one skilled in the art would reasonably understand or infer from a [prior art reference]" that every claim element is disclosed in that reference." AstraZeneca LP v. Apotex, Inc., 2010 U.S. App. LEXIS 22660, at *31 (Fed. Cir., Nov. 1, 2010) (quoting In Re Baxter Travenol Labs, 952 F.2d 388, 390 (Fed. Cir. 1991)).

b. PTO Actions.

In December 2009, the United States Patent and
Trademark Office ("PTO") issued a non-final Office Action in
Ex Parte Reexamination. (Dkt. No. 183, Ex. 10.) The
examiner rejected Claims 1, 2, 4, 5, 7, 8, 9, 16, 21, 22,
23, 25, 26, 30, and 33 of the '699 patent as anticipated by
JP '377. Plaintiffs appealed this rejection, and,
coincidentally, an Ex Parte Reexamination Final Office
Action was issued on the very day that this court held a
hearing on the motions for summary judgment. (Dkt. No. 236,
Ex. 1.) In this action, the PTO partially reversed its
prior decision and found that Claims 1, 2, 4, 5, 25, 26, 30,
33, 35, 36, 39, 40, 47, and 48 were patentable. (Id.) As
of now, then, the PTO has ruled that all of the disputed
independent claims -- namely, 1, 5, and 25 -- are valid.

Defendants submitted supplemental briefs objecting to

the PTO's decision on procedural and substantive grounds.

(Dkt. Nos. 238, 245.) Plaintiffs countered by submitting a copy of the PTO's affirmation of its decision based on further documentation that Plaintiffs sent on November 24, 2010. (Dkt. No. 249, Ex. 1.) This most recent PTO notice reaffirms its finding of validity and states that "[p]rosecution on the merits is (or remains) closed in this ex parte reexamination proceeding." (Id. at 2.)

Defendants contest the PTO's decision on substantive and procedural grounds, arguing that the decision was erroneous and should be disregarded by the court. Neither the procedural nor the substantive argument is persuasive.

As to the procedural grounds, Defendants charge that Plaintiffs misled the PTO and provided an incomplete record. An analysis of the relevant portions of the PTO record provided by both parties, however, reveals no significant evidence of any impropriety of this sort on the part of Plaintiffs.

With regard to Defendants' substantive argument, which focuses on the issue of the core-to-cladding ratio, the court agrees with the PTO that the '699 Patent is valid.

The `699 Patent discloses a core-to-cladding ratio of greater than or equal to 1.4. U.S. Pat. No. 5,428,699, column 15, lines 1-2. Defendants argue that JP `377

discloses the same ratio, and they contest that portion of the PTO's finding of validity that determined that JP '377 disclosed no specific core-to-cladding ratio. The relevant portion of JP '377 is as follows:

the fiber base conductor is a fused silica fiber with a core size of 400µm and with an outer diameter of the cladding layer of 650µm. Over the entire length of fiber base conductor (11), a primary coating layer (12) is formed. Fiber base conductor (11) with said primary coating layer (12) formed on it is further protected by a flexible protective coating tube (13) which can prevent cracks on fiber base conductor (11) or damage by folding of fiber base conductor (11).

(Dkt. No. 183, Ex. 6, Japanese Patent No. 3-63377, at 9.)

The relevant portion of the PTO's finding of validity of the `699 Patent is as follows:

The examiner agrees with the Patent owner's argument that the 650µm in the JP '377 patent corresponds to the outer diameter of the fiber base conductor, which includes the protective coating tube (13) because:

- (i) the JP '377 patent disclosed a "gap (21)" is "set to cover the entire outer circumference of fiber base conductor (11)" . . ., and
- (ii) "leaking beam" problem described in Abe '047 shows that component (11) cannot include both a core (400 μ m) and a cladding layer (650 μ m).

One may argue that the fiber base conductor (11) includes a core and a cladding layer whereas primary coating layer (12) and protective coating layer (13) could not be part of the "core and cladding" of component (11) based on the disclosure at page 9 of the JP '377.

The examiner agrees that the teaching in this passage could be interpreted such as component (11) includes both a core (400µm) and a cladding layer (650µm). However, if the diameter of the cladding were 650µm and the core were 400µm in the component (11), the cladding to core ratio would

be 1.625, then the leaking beam would be insignificant. In the Abe '047 patent, the JP '377 inventors describe a "leaking beam" problem which is generated by a reflecting surface. This "leaking beam" problem would not occur if the fiber base conductor (11) included only a core (400µm) and a cladding layer (650µm) (i.e., the primary coating layer (12) and protective coating layer (13) were not part of the "core and cladding" of component (11)).

If reasons (i) and (ii) discussed above are not totally convinced [sic]; at least, because it is not clear whether the primary coating layer (12) and the protective coating layer (13) are part of the cladding layer in the fiber base conductor (11), JP '377 or Abe '047 cannot anticipate the [above] limitation . . . [because] it is well settled, anticipation cannot be established base [sic] on doubt or possibilities.

(Dkt. No. 249, Ex. 1 at 3-5.)

While the court agrees with the PTO that the disputed language is amenable to more than one interpretation, an additional statement in the patent supports the PTO's finding, and Plaintiffs' position, that JP '377 does not disclose a specific core-to-cladding ratio and therefore does not render the '699 Patent invalid by anticipation.

Defendants contend that JP '377 discloses a fiber base conductor (11) with a core size of 400µm and an outer "cladding layer" that brings the diameter of the fiber base conductor to 650µm. Over this "cladding layer," Defendants argue, JP '377 discloses a "primary coating layer" (12) and a flexible protective coating tube (13). If this were true, Defendants contend, then the core-to-cladding ratio would be

1.625, which is greater than or equal to 1.4, i.e., precisely what is disclosed by the '699 Patent. Plaintiffs argue, conversely, that the outer diameter of 650µm includes the protective tube coating (13) that covers (11) and (12) with the result that JP '377 does not disclose any specific core-to-cladding ratio.

While Defendants' interpretation of the plain language of the claim has some force, "when a party challenges a claim's validity based on prior art, 'the PTO and the court must interpret [a] claim in light of the specification in which it appears.'" Koninklijke Philips Elecs. N.V. v. Cardiac Sci. Operating Co., 590 F.3d 1326, 1335 (Fed Cir. 2010) (quoting Rowe v. Dror, 112 F.3d 473, 479 (Fed. Cir. 1997)). The specification includes the following statement, which is illustrated by Figure 1, reprinted in color in Plaintiffs' expert's report (Dkt. No. 177, Ex. 6, Griffin Rep. ¶ 33): "pressurized air is fed into gap (21) set to cover the entire outer circumference of fiber base conductor (11)." (Dkt. No. 183, Ex. 6, Japanese Patent No. 3-63377, at 10.) The illustration makes clear that the "entire outer circumference of fiber base conductor (11)" includes (12) and (13). No measurements are provided for (12) and (13) and, thus, as the PTO examiner found, JP '377 discloses no specific core-to-cladding ratio.

c. Conclusion on Anticipation.

Given that JP '377 discloses no explicit core-tocladding ratio, the court must conclude that this prior art
does not "disclose every limitation of the claimed
invention, either explicitly or implicitly." LiebelFlarsheim Co. v. Medrad, Inc., 481 F.3d 1371, 1381 (Fed.
Cir. 2007). Defendants have thus failed to provide clear
and convincing evidence that JP '377 anticipated all of the
asserted claims.

Significantly, Defendants have failed to overcome the additional burden of showing that the PTO erred in finding that the '699 Patent is valid. See Pharmastem Therapeutics, Inc. v. Viacell, Inc., 491 F.3d 1342, 1366 (Fed. Cir. 2007) (quoting Polaroid Corp. v. Eastman Kodak Co., 789 F.2d 1556, 1560 (Fed. Cir. 1986)) ("When the party asserting invalidity relies on references that were considered during examination or reexamination, that party 'bears the added burden of overcoming the deference that is due to a qualified government agency presumed to have done its job.'"). The deference that the court is obliged to give to the PTO's findings provides an additional reason for allowing Plaintiffs' motion for summary judgment that the '699 Patent is not invalid based on anticipation.

2. Obviousness.

Defendants also contend, in cursory fashion, that the '699 Patent claims are obvious under 35 U.S.C. § 103 (a), which provides that a patent may not be issued where

the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

35 U.S.C. § 103 (a). See also Great Atl. & Pac. Tea Co. v. Supermarket Equip. Corp., 340 U.S. 147, 152 (1950) ("The conjunction or concern of known elements must contribute something; only when the whole in some way exceeds the sum of its parts is the accumulation of old devices patentable.").

To prove obviousness, Defendants must demonstrate through clear and convincing evidence that "the improvement is more than the predictable use of prior art elements according to their established functions." KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 417 (2007).

Defendants support their claim of obviousness with a two-paragraph argument. Even with the attached comparison charts, Defendants' <u>ipse dixit</u> provides woefully insufficient evidence for the court to conclude that the '699 Patent is obvious. Particularly in light of the discussion above concerning anticipation, no adequate ground exists for any finding as a matter of law that Defendants

have demonstrated obviousness by clear and convincing evidence. As Plaintiffs' submissions make clear, the '699 Patent is manifestly more than a sum of the parts of the two prior patents. Accordingly, the court will allow Plaintiffs' motion for summary judgment on the issue of obviousness.

3. Failure to Meet the Written Description.

Defendants' final argument on invalidity concerns its allegation that the '699 Patent violates 35 U.S.C. § 112, which requires that the specification of a patent include all claims of the patent. See 35 U.S.C. § 112 ("The specification shall contain a written description of the invention and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains . . . to make and use the same"). As Plaintiffs observe, Defendants "bizarrely" argue that the accused product -- i.e., their own device -- does not meet the specifications of the '699 Patent. (Dkt. No. 202, Pl. Mem. in Opp. to Def. Mot. for Summ. J. on Invalidity, at 24.) While certainly relevant in the context of infringement, Defendants' contention that the `699 Patent's specifications disclose a core-to-cladding ratio of 1.4 or greater but that the accused product has a core-to-cladding ratio of 1.1 and

1.06 has no bearing on whether Plaintiffs have met the requirements of 35 U.S.C. § 112. (See Dkt. No. 180, Def. Mem. in Supp. of Motion for Summ. J., at 10.)

For these reasons, the court will allow Plaintiffs' motion for summary judgment that the '699 Patent is valid (Dkt. No. 166), and will deny that portion of Defendants' motion for summary judgment (Dkt. No. 179) seeking a ruling that the '699 Patent is invalid.

C. Count II: Infringement of the '699 Patent.

Plaintiffs have moved for summary judgment that

Defendant has infringed Claims 1-2, 4-5, 7-9, 16, 21-23, 2526, 30, and 33 of the '699 Patent. (Dkt. No. 169.) Their

argument relies on Defendants' alleged infringement of
specific independent claims, Claims 1, 5, and 25. See

Wahpeton Canvas Co. v. Frontier, Inc., 870 F.2d 1546, 1552

n.9 (Fed. Cir. 1989) ("One who does not infringe an
independent claim cannot infringe a claim dependent on (and
thus containing all the limitations of) that claim.").

Defendants have opposed the motion and filed a cross motion
for summary judgment seeking a ruling that the accused
product infringes no claims of the '699 Patent as a matter
of law.

1. <u>Legal Standard for Infringement</u>.

infringes Claims 1, 5, and 25 either literally or under the doctrine of equivalents. This court has already conducted the first step of the two-step analysis required for a determination of infringement, that is, the claim construction. See Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1454 (Fed. Cir. 1998) (en banc). Step two is to compare the properly construed claims to the allegedly infringing device. Id. On a motion for summary judgment, the court looks at the record to ascertain whether

a patentee's expert [has] set forth the factual foundation for his infringement opinion in sufficient detail for the court to be certain that features of the accused product would support a finding of infringement under the claim construction adopted by the court, with all reasonable inferences drawn in favor of the non-movant.

Intellectual Sci. & Tech., Inc. v. Sony Elecs., Inc., 589

F.3d 1179, 1183 (Fed. Cir. 2009). "Summary judgment on the issue of infringement is proper when no reasonable jury could find that every limitation recited in a properly construed claim either is or is not found in the accused device either literally or under the doctrine of equivalents.'" U.S. Phillips Corp. v. Iwasaki Elec. Co., 505 F.3d 1371, 1374-75 (Fed. Cir. 2007) (quoting PC Connector Solutions LLC v. SmartDisk Corp., 406 F.3d 1359, 1364 (Fed. Cir. 2005)). "Literal infringement requires that the accused device literally embodies every limitation of

the claim." Revolution Eyewear, Inc. v. Aspex Eyewear,
Inc., 563 F.3d 1358, 1369 (Fed. Cir. 2009). Under the
doctrine of equivalents, the accused claim must include
"every element or its substantial equivalent." Zygo Corp.
v. Wyko Corp., 79 F.3d 1563, 1568 (Fed. Cir. 1996). While
absence of a single limitation is sufficient to overcome an
allegation of infringement, "[i]f, in the context of the
invention, the substituent substantially performs the same
function to achieve the same result in the same way as the
required limitation, that limitation is satisfied." Id.

2. Claim 1.

The limitations of claim 1 are as follows:

An apparatus for communicating and laterally

directing electromagnetic radiation, comprising: [element 1] a wave guide having a tip for communicating electromagnetic radiation in a propagation direction to the tip of the waveguide; [element 2] a transmitting surface on the tip of the wavequide; [element 3] a reflecting surface on the tip of the waveguide for internally reflecting electromagnetic radiation communicated by the waveguide in a direction lateral to the propagation direction toward a particular area on the transmitting surface; and [element 4] wherein the particular area and the reflecting surface are disposed so that greater than about 90% of electromagnetic radiation reflected by the reflecting surface is incident on the particular area at below a critical angle for transmission through the transmitting surface in the lateral direction.

U.S. Pat. No. 5,428,699, column 14, lines 47-64.

Defendants concede that the accused product includes

elements 1 and 3. (Dkt. No. 171, Ex. 10, Defs.' Response to Req. for Admis., ¶¶ 1, 14.) The court's task, therefore, is to determine whether Defendants' product also includes both elements 2 and 4.

a. <u>Literal Infringement of Element 2 of Claim 1</u>.

At the core of the infringement argument is the question whether the accused product has "a transmitting surface on the tip of the waveguide" as recited by element 2.

In his expert report, Defendants' expert, Dr. Irving J. Bigio, described the transmitting surface of the accused device as "located on the external surface of the cap. The cap is not part of the tip of the waveguide. . . . Rather, the cap is fused to the silica sleeve and the silica sleeve is, in turn, fused to the core cladding." (Dkt. No. 171, Ex. 4, Bigio Rep. ¶ 23.) He explained further that this "transparent cap . . . is not part of the waveguide but rather is a separate component that is fused to the waveguide." (Id. ¶ 44.) Later in his report, in a different context, he repeated that the "cap is not part of the tip of the waveguide, and the tip of the waveguide does not include any transmitting surface." (Id. ¶ 45.)

Plaintiffs' expert, Dr. Thomas D. Milster, opined, on the other hand, that because the transmitting surface is on the

cap, part of which is fused to the tip, it should be contrued as "on the tip." (Dkt. No. 171, Ex. 2, Milster Rep. ¶ 102.)

The parties did not ask this court to construe either the term "on the tip of the waveguide" or the term "cap."

However, as this court noted in its Markman Order, Judge

Joan N. Erickson of the District Court of Minnesota

construed a number of terms in the '699 Patent with regard

to Plaintiffs' case in her district. See Am. Med. Sys. v.

Laser Peripherals, LLC, 665 F. Supp. 2d 1025, 1037-38 (D.

Minn. 2009). As this court further observed regarding a

term that Judge Erickson had previously construed, "[g]iven

the awkwardness posed for the parties were different

district courts to construe the same patent term

differently, and the sound foundation for Judge Erickson's

construction, this court will adopt her construction of the

term 'glass cladding.'" Markman Order, at *221.

The court now holds that the same is true for Judge Erickson's construction of "tip of the waveguide" and "cap." In her thoughtful, reasoned opinion, Judge Erickson construed the cap as a "separate element[] from the 'tip of the waveguide.'" First, she noted that "Claim 20 recites 'a transparent cap, secured to the tip and enclosing the reflecting surface and the transmitting surface.' (Emphasis

added.)." Am. Med. Sys., 665 F. Supp. at 1037. She continued:

This claim language indicates that the . . . "cap" [is a] separate element[] from the "tip of the waveguide." AMS contends that claim 19, which recites the apparatus of claim 7 further comprising "a transparent cap secured to the waveguide and enclosing the reflecting surface on the tip," supports a construction of "tip of the waveguide" that includes a tube or cap. The Court does not agree.

Id. at 1037-38. Judge Erickson concluded, and this court agrees, that "[a] transparent cap that 'enclos[es] the reflecting surface on the tip' plainly is a separate component from the tip." Id. To construe the cap of the accused product as a part of the tip would require the court to disregard both common sense and Judge Erickson's express construction to the contrary, which the court declines to do.

The court further disagrees with Plaintiffs' argument that a determination that the transmitting surface of the accused product is not located on the tip of the waveguide would contradict this court's construction of the term "transmitting surface." It is true that this court rejected Defendants' proposed definition of "transmitting surface" as too limiting because it required a location "on the outer surface of a round core cladding on the waveguide." Markman Order, at 5. Instead, the court construed "transmitting

surface" as "surface through which electromagnetic radiation is transmitted in the lateral direction." Id. at 16.

Contrary to Plaintiffs' contention, however, the court's finding that the cap and the tip of the waveguide on the accused product are two different components does not contradict this construction. It is the '699 Patent, and not the court's construction, that requires the transmitting surface to be "on the tip of the waveguide." The contested issue that the court is resolving here is not what comprises the transmitting surface but rather where it is located. The accused product has a transmitting surface but it is undisputed that this surface is located on the cap and not on the tip of the waveguide.

Plaintiffs also argue that, even if the transmitting surface is located on the cap and not directly on the tip, it can still be found to be "on" the tip, just as the apple mentioned in the first paragraph of this memorandum may be considered to be "on" the table even though it sits on a dictionary without physically touching the table. (See Dkt. No. 171, Ex. 2, Milster Rep. ¶ 102.)

This is a clever argument, but, in this context, it will not fly. Although the court has not yet formally construed the term "on," its ordinary dictionary definition is "a function word to indicate position in contact with and

supported by the top surface of as in "the book is lying on the table." Merriam-Webster's Dictionary (2011) (emphasis in original). See Hockerson-Halberstadt, Inc. v. Avia Group Int'l, 222 F.3d 951, 955 (Fed. Cir. 2000) ("[T]he court gives claim terms their ordinary and accustomed meaning as understood by one of ordinary skill in the art."). Here, where element 2 of Claim 1 of the '699 Patent recites "a transmitting surface on the tip of the waveguide," the court finds that the transmitting surface must be actually on (in the sense of "in contact with") the tip of the waveguide.

In the face of this determination, it is clear that no reasonable jury could find that the accused product literally infringes element 2 of Claim 1.

b. <u>Infringement of Element 2 of Claim 1 under the Doctrine of Equivalents</u>.

Plaintiffs argue alternatively that the accused product infringes Claim 1 under the doctrine of equivalents. "A finding of infringement under the doctrine of equivalents requires a showing that the difference between the claimed invention and the accused product was insubstantial." Crown Packaging Tech., Inc. v. Rexam Bev. Can Co., 559 F.3d 1308, 1312 (Fed. Cir. 2009). The Supreme Court has articulated the "essential inquiry: Does the accused product or process contain elements identical or equivalent to each claimed element of the patented invention?" Warner-Jenkinson Co. v.

Hilton Davis Chem. Co., 520 U.S. 17, 39 (1997). Practically speaking, "[t]he determination of equivalence should be applied as an objective inquiry on an element-by-element basis." Id. at 40.

To find infringement under the doctrine of equivalents on element 2 of Claim 1, the court would have to determine that a transmitting surface located on the cap that covers the tip of the waveguide "'performs substantially the same function in substantially the same way to obtain the same result'" as a transmitting surface located on the tip of the waveguide. Sanitary Refrigerator Co. v. Winters, 280 U.S. 30, 42 (1929) (quoting Machine Co. v. Murphy, 97 U.S. 120, 125 (1878)). Significantly, the query is not whether the claimed and accused devices perform a similar function, which, as lasers that treat BPH, indisputably, they do. Instead, the question is whether the contested element of the accused device performs substantially the same function in substantially the same way as its alleged counterpart element in the claimed device.

The significance of the difference between a transmitting surface located on a cap that covers the tip of the wave guide and a transmitting surface located on the tip of the wave guide itself, was explicitly recognized by Russell Pon, the inventor of the '699 patent. Dr. Pon

testified that his patent disclosed a cap attached to the waveguide with an adhesive. (Dkt. No. 171, Ex. 32, Pon Dep. 76:18-77:9.) Despite the adhesive, an "air gap" would form between the tip of the fiber and the inner diameter of the cap, both of which, as well as the outer diameter of the cap, are transmitting surfaces. (Id. at 83:17-84:12.) He testified that prior to the conception of the '699 patent, he "was not aware of or had not attempted to at that time do any fusing or welding in the transmitted area or in the tip region." (Id. at 103:5-8.) In an attempt to eliminate the air gap between the interior diameter of the cap and the fiber, he later sought, after receiving the '699 patent, "to fuse a cap to a fiber so as to eliminate the air gap between the first and second transmitting surfaces." (Id. at 104:21-24.) When asked whether he had intended "to disclose in your patent application fusing a cap to the fiber tip all the way up to the beveled edge so that the air gap between the first and second transmitting surfaces would be eliminated," Dr. Pon responded, "not necessarily all the way up to the beveled surface." (Id. at 115:19-25.) When asked, "[d]id you intend to disclose in your patent application fusing the cap to the fiber," he answered, "I don't recall." (<u>Id.</u> at 116:4-6.)

Plaintiff's expert, Steven E. Griffin, testified that he had received a patent for an improvement on the '699

Patent design through which "the glass cap is fused to the transmitting surface of the fiber that - making the cap diameter itself the transmitting surface such that it's effectively an overclad fiber." (Dkt. No. 171, Ex. 31, Griffin Dep. 98:25-99:3.) Mr. Griffin's patented design did not take hold at the time. However, he testified that the fusion of the cap to the fiber significantly reduced "the reduction of distortions" making the design "far superior to that afforded by Pon." (Id. at 98:5-7.)

Dr. Bigio echoed this point, explaining that the cap serves a specific purpose, which is "to achieve better optical efficiency." (Dkt. No. 171, Ex. 5, Bigio Rebuttal Rep. ¶ 39.) Additionally, Brian Foley, Defendant Biolitec's Chief Operating Officer, testified at length about the cap, noting that the cap itself impacts the percentage of light that is refracted in the lateral direction. (Dkt. No. 171, Ex. 33, Foley Dep. 107:5-109:24.) He also testified that a former employee of Defendant Biolitec, Joe Brown, invented "the fused cap design" in the early 1990s. (Id. at 158:14-159:8.)

Given this evidence that the fusion of the cap to the

fiber has the intended result of creating a transmitting surface on the cap and not separated from the cap by an air gap, the court cannot conclude that the transmitting surface on the cap "performs the same function to achieve the same result" as the transmitting surface on the tip of the wavequide. Zygo Corp. v. Wyko Corp., 79 F.3d 1563, 1568 (Fed. Cir. 1996). See also Atlas Powder Co. v. E.I. du Pont <u>de Nemours & Co.</u>, 750 F.2d 1569, 1579-80 (Fed. Cir. 1984) ("Where, as here, the accused product avoids literal infringement by changing one ingredient of a claimed composition, it is appropriate for a court to consider in assessing equivalence whether the changed ingredient has the same purpose, quality, and function as the claimed ingredient."). The court thus finds that the accused product does not infringe element 2 of Claim 1 under the doctrine of equivalents.

This finding obviates the need for the court to determine whether element 4 of Claim 1 is infringed because infringement "requires that each and every claim limitation be present in the accused product." Abraxis Bioscience,

Inc. v. Mayne Pharma Inc., 467 F.3d 1370, 1378 (Fed. Cir. 2006). On the same basis, the court need not analyze whether the accused product infringes Claims 5 and 25 of the '699 Patent. Having determined that the accused product

does not infringe Claim 1, the court will accordingly allow Defendants' motion for summary judgment on Count II as to infringement.

D. <u>Count III: False Advertising under the Lanham Act</u>.

Plaintiffs and Defendant Biolitec have filed cross motions seeking summary judgment on Count III, false advertising under the Lanham Act, 15 U.S.C. § 1125(a). Here, Plaintiffs' claim is exceedingly narrow, focusing on a single graph that Defendant Biolitec, for a limited time period, included in its sales powerpoint presentation and brochure. (Dkt. No. 177, Ex. 1, at B004308.) Plaintiffs allege that the graph, entitled "Penetration Depth," falsely portrayed their GreenLight system as having a dangerously high penetration depth and falsely attributed a low penetration depth to Defendants' Evolve system. Defendant Biolitec denies that the portrayals are inaccurate and argues that, in any event, the relevant consumers (urologists) are too sophisticated to be swayed by one graph on a twenty-one slide powerpoint presentation, or in a minor feature of a brochure, when making a major purchase of medical equipment.

1. The "Penetration Depth" Graph.

It is not disputed that, for some period of time,
Defendant Biolitec's sales force used the "Penetration

Depth" graph in its powerpoint presentation and in a brochure. (Dkt. No. 177, Ex. 1, at B004308.) Defendant Biolitec ceased using the contested graph in October 2009. (Dkt. No. 183, Ex. 41, Foley Decl. ¶ 3.) The graph depicts the penetration depth of the wavelengths of four products into pigmented and unpigmented tissue. The penetration depth refers to "the depth at which the concentration of light decreases to about 37% of its original concentration." Markman Order, at 6. The four products in the graph are identified as "KTP," "Nd," "Ho," and "980." The specific penetration depth is represented by a colored bar.

Plaintiffs allege, and Defendants do not dispute, that the green line labeled "KTP" with a penetration depth of 4.0 represents their product, and the red line labeled "980" with a penetration depth of less than 1.0 represents Evolve. Plaintiffs further allege that the penetration depth assigned to the GreenLight system is grossly exaggerated and suggests that the system is dangerous. Moreover, they state, the penetration depth assigned to the Evolve system is understated. Although the graph identifies neither GreenLight nor Evolve by name, Plaintiffs allege that their sales and reputation have been negatively impacted by Defendants' use of this graph. Specifically, they allege

that "many customers switched from AMS lasers to Biolitec lasers" as a result of this graph. (Dkt. No. 175, Pls.' Mem. in Supp., at 7.)

2. Legal Standard.

The Lanham Act prohibits duplications advertising in interstate commerce, including misleading or false descriptions of products. 15 U.S.C. § 1125(a). To prove a claim of false advertising, a plaintiff must demonstrate:

(1) the defendant made a false or misleading description of fact or representation of fact in a commercial advertisement about his own or another's product; (2) the misrepresentation is material, in that it is likely to influence the purchasing decision; (3) the misrepresentation actually deceives or has the tendency to deceive a substantial segment of its audience; (4) the defendant placed the misleading statement in interstate commerce; and (5) the plaintiff has been or is likely to be injured as a result of the misrepresentation, either by direct diversion of sales or by a lessening of goodwill associated with its products.

Cashmere & Camel Hair Mfrs. Inst. v. Saks Fifth Ave., 284

F.3d 302, 310-11 (1st Cir. 2002). As with all motions for summary judgment, a motion for summary judgment on a claim of violation of the Lanham Act requires the nonmoving party to "'establish a trial-worthy issue by presenting enough competent evidence to enable a finding favorable to the nonmoving party.'"

Id. at 308 (quoting Leblanc v. Great Am. Ins. Co., 6 F.3d 836, 842 (1st Cir. 1993)). Here, the court

need not determine whether the information on the graph was false because, as explained below, Plaintiffs have failed to provide any evidence on which a jury could find that they were injured as a result of the alleged misrepresentation of the penetration depth of the GreenLight laser.

3. Presumptions.

As a threshold issue, it is true, as Plaintiffs state, that where there is literal falsity, the court applies a "presumption of consumer deception." Id. at 314. This presumption does not assist Plaintiffs here, however, because, even if the court determined that the graph portrayed information that was literally false and, thus, that consumers were in fact deceived, Plaintiffs have nevertheless failed to show any injury. Moreover, even if the court adopted, as Plaintiffs urge, a presumption of injury due to literal falsity, Defendants have conclusively

⁵ Although several circuits have recognized this presumption, the First Circuit has not. <u>See, e.g.</u>, <u>Porous Media Corp. v. Pall Corp.</u>, 110 F.3d 1329 (8th Cir. 1997); <u>McNeilab, Inc. v. Am. Home Products Corp.</u>, 848 F.2d 34 (2d Cir. 1988). Issues raised by these courts include whether such a presumption is warranted where plaintiffs are seeking injunctive relief and monetary damages and whether the presumption should only be found where the false advertising specifically mentioned the plaintiff's product. <u>See Porous Media Corp.</u>, 110 F.3d at 1333-36. Additionally, whether the

rebutted the presumption with overwhelming, uncontroverted evidence that doctors, in fact, stopped buying GreenLight because they found it to be less effective than other products on the market, including, but not limited to, Defendant Biolitec's product.

4. Evidence of Injury.

"In order to prove causation under § 1125(a) of the
Lanham Act, the aggrieved party must demonstrate that the
false advertising actually harmed its business." Id. at
318. Because Plaintiffs' allegations solely concern the
"Penetration Depth" graph, they must demonstrate that the
graph actually resulted in lost sales and good will.

Assuming arguendo that Plaintiffs can prove decreased sales
generally, they have offered no evidence that the graph
itself caused any urologist not to purchase GreenLight. On
the other hand, Defendants have offered powerful evidence
demonstrating that any lost sales were due directly to

advertising was comparative or simply false is dispositive in some circuits. <u>See, e.g.</u>, <u>McNeilab, Inc.</u>, 848 F.2d at 38. Here, the chart compared Evolve and GreenLight as well as two other laser products, making this case somewhat of a hybrid. Either way, the court declines to apply such a presumption on these facts.

GreenLight's defects.

First, regarding the impact of the graph on consumers, i.e., urologists, the only evidence of record pertaining to impact comes from Dr. David Turk, a urologist who became a Medical Director of Defendant Biolitec. Dr. Turk testified that he gave presentations about Evolve to other doctors relating his "own experience with laser vaporization [and with] the Evolve laser." (Dkt. No. 177, Ex. 11, Turk Dep. 11:8-11.) He stated that he would use the powerpoint presentation provided to him by Defendants but "did not elaborate on it. And I was mainly relaying my personal experience with the laser." (Id. at 34:1-3.) As a consumer of the product, Dr. Turk stated that "the slide does not mean anything to me as far as -- as far as my interpretation of how the green -- how effective the Greenlight is. I work on a clinical basis." (Id. at 40:1-5.)

As to lost sales, the record includes damaging statements from urologists about why they stopped using the GreenLight laser. Dr. Turk testified that he used the GreenLight laser from 2002 through 2006. (Id. at 26:5-8.)

As recently as one month prior to his deposition, he had tried a new version of the GreenLight system that Plaintiff AMS had provided him. (Id. at 26:15-20.) Dr. Turk stated

system, salespeople from Plaintiff AMS would explain that the Greenlight "was not effective without -- without hemoglobin present in the tissue. . . And this is the main reason why I became dissatisfied with the AMS product, because it was -- it was not working as well as it should."

(Id. at 44:20-45:15.) Dr. Turk continued, "the Greenlight laser is uncontrolled . . . you can burn areas, you can drill a hole into the prostate, you can -- it's not as controlled as Evolve. It's a very different laser." (Id. at 98:16-22.) He stated further, "It is my clinical experience that I get better vaporization of the prostate with the Evolve laser . . . in comparison to the Greenlight. . . . It's a better laser." (Id. at 148:14-20.)

Dr. Swierzewski, Medical Director of United Medical Systems, a company that sells surgical equipment to urologists, testified that the Evolve laser works differently than and is superior to the GreenLight laser.

(Dkt. No. 183, Ex. BBB, Swierzewski Dep. 218:20-221:10, 230). He stated, "[s]peaking from the point of a Medical Director of UMS, my understanding is that . . . urologists are converting from the Greenlight to the Biolitec laser because they like it better." (Id. at 208:23-209:4.)

Drew Forhan, who founded ForTec, a company that sold both products, testified that in 2006, when the company first began selling the Evolve system, sales for the GreenLight system went down. (Dkt. No. 177, Ex. 25, Forhan Dep., 142:7-14.) However, he also testified that a product called HPS, which employed a "newer technology," was introduced around the same time and that sales of GreenLight would have decreased as a result of HPS's presence in the market even if Evolve had not been introduced. (Id. at 144:16-22.)

Plaintiffs have provided no evidence to counter any of these statements. Without evidence of any urologist who chose Evolve over GreenLight due to the graph -- nor even any urologist who chose Evolve over GreenLight after trying both lasers -- Plaintiffs have failed to demonstrate any injury caused by the allegedly false graph. Significantly, Plaintiffs' evidence that Defendant Biolitec's salespeople sought to convince urologists to use Evolve instead of GreenLight provides no support for the false advertising claim. Clearly, manufacturers are entitled to encourage consumers to use their product over others on the market.

The absence of sufficient evidence in the record to satisfy Plaintiff's burden on the fifth element of their Lanham Act claim compels the court to allow Defendants'

motion for summary judgment on Count III.

E. Count IV: Violation of Mass. Gen. Laws ch. 93A.

Plaintiffs argue that Defendant Biolitec's use of the allegedly deceptive graphs constituted an "[u]nfair method[] of competition and unfair or deceptive act[] or practice[]" in violation of the Massachusetts Consumer Protection Act. Mass. Gen. Laws, ch. 93A, § 2.6 This allegation fails for the same reasons as noted above. Even accepting Plaintiffs' allegations of misrepresentation as true, there simply is no evidence of a causal relationship between the graph itself and any decrease in sales of Plaintiffs' GreenLight product. Heller Financial v. Insurance Co. of N. Am., 573 N.E. 2d 8, 16 (Mass. 1991) ("[T]he evidence must warrant a finding that a causal relationship existed between the misrepresentation and the injury."). Accordingly, the court will allow Defendants' motion for summary judgment on Count IV.

E. Count V: Violation of Mass. Gen. Laws ch. 266, § 91.

⁶ Although not raised by Defendants, the court also observes that none of the conduct at issue is alleged to have occurred in Massachusetts. <u>See</u> Mass. Gen. Laws ch. 93A, §11 ("No action shall be brought or maintained under this section unless the actions and transactions constituting the alleged unfair method of competition or the unfair or deceptive act or practice occurred primarily and substantially within the commonwealth.").

Jurisprudence concerning Mass. Gen. Laws ch. 266, § 91, is remarkably scant. Thus, with no guidance on the statute's application from case law, nor any suggestion by either party that the state claims be considered differently from the federal claims, the court will follow the authority from this district, to the effect that "the state analogue prohibiting false advertising . . . rises or falls with the federal claim." Holmes Group, Inc. v. RPS Prods., 424 F. Supp. 2d 271, 289, n.18 (D. Mass. 2006). Plaintiffs have not alleged any unfair business practices other than those alleged in the false advertising claim. Accordingly, the court will allow Defendants' motion for summary judgment on Count V.

F. Count VI: Unfair Competition.

Plaintiffs allege that Defendant Biolitec's wrongful conduct violates Massachusetts common law. (Dkt. No. 72, First Am. Compl. ¶ 64.) The allegations include only those of false advertising. Plaintiffs' brief in support of their motion for summary judgment does not expand on this claim, nor does their brief in opposition to Defendants' motion. With no legal support offered in support of the claim, the court will allow Defendants' motion for summary judgment on

Count VI.

IV. CONCLUSION

While the '699 Patent is valid, Defendants' accused device simply did not infringe; nor did Defendants commit a Lanham Act violation. For the reasons set forth above, Defendants' Motion for Summary Judgment on all counts (Dkt. No. 179) is hereby ALLOWED. Plaintiffs' Motion for Summary Judgment that the Asserted Claims are Not Invalid (Dkt. No. 166) is hereby ALLOWED. Plaintiffs' Motion for Summary Judgment of Infringement (Dkt. No. 169) is hereby DENIED. Plaintiffs' Motion for Summary Judgment of False Advertising under the Lanham Act and Unfair and Deceptive Trade Practices under Massachusetts Law (Dkt. No. 174) is hereby DENIED. Defendants' Motion to Strike (Dkt. No. 184) is hereby DENIED AS MOOT. Plaintiffs' Motion to Preclude (Dkt. No. 188) is hereby DENIED AS MOOT, and the court notes that it relied on none of the contested evidence in forming its decision. Defendants' Motion to Compel (Dkt. No. 218) is hereby DENIED AS MOOT.

Count I of infringement of the '764 Patent against

Defendants CeramOptec Industries, Inc., CeramOptec GmbH, and

AndaOptec, Ltd. is all that remains in this case. Defendant

Biolitec is no longer a party. Plaintiffs have made the

allegations in Count I against Defendant Biolitec in a

parallel suit, C.A. 07-cv-30109-MAP. A status report will be filed by Plaintiffs, confirming their intention to pursue Count I and proposing a schedule for further proceedings, on or before April 11, 2011.

It is So Ordered.

/s/ Michael A. Ponsor MICHAEL A. PONSOR U. S. District Judge